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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,947	12/24/2003	Kenji Fukuta	ONO-109	9577
35777	7590	05/03/2007	EXAMINER	
SHERMAN & ASSOCIATES 415 NORTH ALFRED STREET ALEXANDRIA, VA 22314			HUH, BENJAMIN	
		ART UNIT	PAPER NUMBER	
		3767		
		MAIL DATE	DELIVERY MODE	
		05/03/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/743,947	FUKUTA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Benjamin Huh	3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 31 January 2007.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4-7 and 9 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4-7 and 9 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-7, & 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 states that the cross-linked ion-exchange resin is a cation-exchange resin OR an anion-exchange resin, the way the claim is written technically both sides of the bag can be anion or cation since the resin placed in both sides can be one or the other. Therefore the claim does not distinctly claim and point out the subject matter regarded as the invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 & 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumura et al (US Pub. No. 2005/0070840A1) in view of Sibalis (US Patent No. 4713050). The Matsumura et al reference discloses an iontophoresis

device that has an working electrode 11 connected to a medical instrument (13,14,15), consisting of a anion-exchange membrane & a cation-exchange membrane connected to a ionic medicine, and a counter electrode 21 connected to the working electrode 11 through a cell 3 and utilizes a electrolyte layer 12 to connect the working electrode 11 to a medical instrument (13,14,15). Matsumura also discloses the membrane to comprise a film or sheet and to have a porosity within the range of 20% to 95%, see para [0218] – [0222], and for the pores to have a filling ratio of from 5% to 95% by weight, see para [0211] – [0212]. The Matsumura reference clearly shows the anion membrane and the cation membrane surrounding the ionic medicine. Now even though Matsumura does not explicitly disclose the medicine sealed in a bag attention is directed to Sibalis. The Sibalis reference teaches a device that utilizes medicine, which can be sealed in a bag, see col. 3 lines 22-41. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Matsumura et al with the device of Sibalis in order to create a bag for the medication that is to be delivered that prevents leakage of the drug and to help contain the drug. Also wherein the "... by melt-adhering ..." is deemed to be written in product by process language and since the bag is sealed it would inherently be able to have been sealed by that process, also it would be obvious for one of ordinary skill in the art to utilize melt-adhering to seal and form the bag since it is well known to do so not just in the medical art but also generally in sealing bags.

Art Unit: 3767

With respect to claim 4, wherein the ionic-medicine substance is a sheet impregnated with a solution of an ionic medicine, see para [00121] Matsumura.

With respect to claim 6, wherein the membranes are fully capable of contacting the surface of a living body due to it's size, shape, and ability to work in the environment.

Claims 7 & 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumura et al (US Pub. No. 2005/0070840A1) in view of Sibalis (US Patent No. 4713050) as applied to claim 6 and further in view of Theeuwes et al (US Patent No. 5169382). Now even though the device of Matsumura in view of Sibalis does not explicitly disclose the use of a flexible armoring member for the electrodes attention is directed to Theeuwes. The Theeuwes reference teaches a flexible armoring member 22 in figure 1 on the device. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Matsumura with the device of Theeuwes in order to provide a flexible protecting member for protecting the components of the device from damage.

With respect to claim 9, wherein the electrolyte layer connects the working electrode to the medical instrument, see figures 3 & 4 Matsumura, and wherein the layer is in the form of a paste or a gel, see para [0122] Matsumura.

Claims 1, 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumura et al (US Pub. No. 2005/0070840A1) in view of Kedem et al (US Patent No. 4217200). Matsumura et al reference discloses an iontophoresis

Art Unit: 3767

device that has an working electrode 11 connected to a medical instrument (13,14,15), consisting of a anion-exchange membrane & a cation-exchange membrane connected to a ionic medicine, and a counter electrode 21 connected to the working electrode 11 through a cell 3 and utilizes a electrolyte layer 12 to connect the working electrode 11 to a medical instrument (13,14,15). Matsumura also discloses the membrane to comprise a film or sheet and to have a porosity within the range of 20% to 95%, see para [0218] – [0222], and for the pores to have a filling ratio of from 5% to 95% by weight, see para [0211] – [0212]. Now even though Matsumura does not explicitly disclose the use of utilizing an ion-exchange membrane bag attention is directed to Kedem. The Kedem reference teaches the use of heat-sealed anion-exchange membrane & cation-exchange membrane bags see col. 1 line 35 – col. 2 line 26. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device of Matsumura with the device of Kedem in order to provide a convenient disposable and/or interchangeable medical instrument and for providing a dual sided ion exchange membrane.

### ***Response to Arguments***

Applicant's arguments filed 1/31/07 have been fully considered but they are not persuasive.

Applicant argues that Matsumura does not describe or suggest sealing an ionic medicine in a bag, the examiner would like to note that this point is moot.

The Sibalis and Kedem references are utilized for their teachings specifically for that point.

Applicant argues that Matsumura and Sibalis fails to disclose the porosity of 20%-95% and the filling ratio from 5% - 95%, the examiner disagrees. The Matsumura reference discloses the porosity of the membranes and the filling ratio in para [0211]-[0212] &[0218]-[0222]. Matsumura discloses the membrane to comprise a film or sheet and to have a porosity within the range of 20% to 95%, see para [0218] – [0222], and for the pores to have a filling ratio of from 5% to 95% by weight via the degree of impregnation, see para [0211] – [0212]. As for Sibalis, this point is moot since the reference of Matsumura is utilized to establish these limitations.

Applicant argues that Kedem is not suitable for contacting the body, the examiner disagrees and notes that the point is moot. The Kedem reference is only utilized for the teachings of the bag, also it is the examiner's position that the device of Kedem would still be fully capable of contacting the body due to its size, shape, and ability to work in the environment but the point is moot since the membranes of the primary reference of Matsumura are fully capable of contacting the body.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 3767

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

*Kevin C. Sirmons*